

Remarks

Claims 1-20 are in the case. Claims 5 and 11-12 have been withdrawn pursuant to restriction and election requirements. Claims 1-4 and 6-10 stand rejected. New claims 13-20 are presented. No new matter has been added by the amendments.

Restriction Requirement

In view of the similarity in the structure and elements of the method and instrument claims and applicant's concern that a showing of distinctiveness has not been made, applicant admits that the methods of claims 11-12 would have been obvious over the claims drawn to the instruments within the meaning of 35 U.S.C. 103. Therefore restriction should not be required. See MPEP § 803; *In re Lee*, 199 USPQ 108 (Comm'r Pat. 1978).

Claim Objections

Claim 2 has been amended in the manner requested by the Examiner.

Claim Rejections – 35 USC § 112

In original claim 1, the first instance of "members" should instead have read "fins." The current amendment corrects this typo and provides antecedent basis for the second mention of "fins."

Claim Rejections – 35 USC § 103

Claims 1-4 and 6-10 stand rejected under §103(a) as being unpatentable over Deyerle (U.S. 4,671,275) in view of Mackwood Ling et al. (U.S. Patent 6,241,772). Applicant traverses on grounds that a prima facie case of obviousness has not been established. There is no suggestion or motivation to combine the centralizer of Mackwood Ling with a rasp, and the record is clear that it was applicant, not the cited references, who identified the shortcoming of Deyerle and taught the solution.

The Examiner takes the position that Deyerle discloses the claimed invention with the exception of the bullet-shaped distal tip comprising three or four fins, spaced at 90 degree spaced locations about the central longitudinal axis, extending radial to the central longitudinal axis and

extending longitudinally, distally from the forward end of the body to converge at an apex aligned with the central longitudinal axis, the fins being disposed inwardly. The Examiner interprets Mackwood Ling et al. as disclosing, with reference to Figure 4, a centralizing device for the stem of a prosthesis, including a bullet-shaped distal tip having the foregoing characteristics. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to construct the device of Deyerle with a bullet-shaped distal tip having the characteristics of Mackwood Ling's centralizer, the fins being disposed inwardly in order to centralize the device at the distal end.

The Examiner points to no suggestion, teaching or motivation in the cited references to provide Deyerle's femoral rasp with a centralizer. In addition to lack of a suggestion or teaching to combine the cited reference, there is also no motivation to do so because the instrument of Mackwood Ling is used in a very different situation, and to solve a very different problem, than the instruments of Deyerle and applicant. In particular, Mackwood Ling's centralizer instrument is used to centralize a cemented femoral prosthetic stems *after* the femoral canal has been prepared, whereas applicant and Deyerle's instruments are used to prepare the femoral canal for receipt of a stem. As noted in the background of Mackwood Ling, the problem of centering a cemented stem in a cement mantel was long known, and various efforts had been made to provide centralizers for use in centralizing cemented femoral stems. However, Mackwood Ling provides no discussion of the preparation of femoral canals, and instead assumes the existence of a properly prepared canal. Deyerle, on the other hand, is directed to a rasp for preparing a femoral canal, but makes no reference to problems with centering the rasp. Nowhere do Mackwood Ling or Deyerle identify the problem of centering a broach for use in preparing the femoral canal to receive a stem.

The record is clear that it was applicant who identified the problem of centering a broach when preparing a femoral canal, and that applicant did so with specific reference to the teaching of Deyerle. In applicant's background section, applicant states:

In the Deyerle patents, the cutting or working sections of the rasps terminate at flat distal end surfaces which lead the rasps into the bone. The distal end configurations of prior rasps and broaches fail to provide any structure for centering the rasps and broaches in the intramedullary canals of the bones prior to the cutting teeth engaging cortical bone. As such, prior rasps and broaches may be introduced into the intramedullary canal off-center, such that the cutting teeth

of the rasps and broaches do not evenly engage cortical bone as the rasps and broaches are advanced into the canals.

(Applicant's specification, p. 2, lines 19-26). Thus, applicant identified the shortcoming of Deyerle and then provided the solution. In the absence of some teaching, suggestion or motivation to combine the cited references, it is respectfully suggested the obviousness rejection is based on hindsight reconstruction, with applicant's disclosure being used as a blue print to construct the claimed invention.

It is also unclear to applicant how putting a centralizer of the type described in Mackwood Ling on a rasp would achieve the objective of the present invention. References are not properly combinable if their intended function is destroyed. See e.g. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). The Mackwood Ling centralizer has an annular opening that is designed to receive a cemented stem having an annular cross-section. It seems clear that a centralizer configured to fit on a stem could not be used in broaching procedure. Mackwood Ling's centralizer would have to be completely modified, using the teaching of applicant's disclosure, and the intended function of Mackwood Ling's centralizer would be destroyed.

For all of the foregoing reasons, applicant respectfully suggests that a *prima facie* showing of obviousness has not been established.

New Claims

New claims 13-16 depend directly or indirectly from claim 1, while claims 17-20 depend directly or indirectly from claim 2. The new claims are based on the previously submitted dependent claims, and add further structure to the claim dependencies.

Conclusion

For the foregoing reasons, it is respectfully suggested that the claims are now in condition for allowance.

It is believed that this response has been filed within the applicable time period for responding and that no extension of time is therefore required, but if an extension is required, applicant hereby requests an appropriate extension of time. It is further believed that no fees are

due, but if any fees or credits are due, the Commissioner is authorized to charge or deposit them to Deposit Account No. 502795.

Respectfully submitted,



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